

### **REMARKS/ARGUMENTS**

Claims 1-45 are pending in the present application. Claims 1-45 were rejected in the Office Action. Claims 4-8 were objected to. Claims 1, 15, 22, 23, 26, 27, 28, 32, 36, 37, 41 and 45 were amended. Claim 46 has been added. No new matter has been added. Re-examination and reconsideration of the pending claims as amended are respectfully requested.

#### **Double Patenting**

Claims 1, 4, 7, 12-18, 19, 22-44, 43, 65 and 66 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting over co-pending Application 10/306,813 in view of Konya, U.S. Patent No. 6,123,723 (hereinafter referred to as Konya). Applicants note that claims 65 and 66 do not currently exist in the present application.

Claims 1, 4, 7, 12, 16-18, 22-28, and 32-37 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting over co-pending Application No. 10/412,714 in view of Konya.

Claims 1-3, 12, 16-18, 22-28 and 32-40 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting over co-pending Application No. 10/944,282 in view of Konya.

Claims 1-3, 12, 16-18, 22-28, 32-37 and 41-44 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting over co-pending Application No. 10/794,405 in view of Konya.

Independent claims 1 and 32 have been amended to recite in part the limitation that the implantable carrier or implantable membrane is dividable at a plurality of locations along its length. Claims 1 and 32 were also amended to recite in part that a distal portion of the expandable member expands a distal portion of the implantable carrier or implantable membrane and at least one stent segment disposed thereon while a second portion of the implantable carrier or implantable membrane remains unexpanded within the sheath. Additionally, claims 1 and 32 have also been amended to recite in part that the sheath is adapted to divide the implantable

carrier or the implantable membrane at one of the locations. Similarly, independent claim 41 has been amended to recite in part the step of dividing the implantable carrier between the distal and proximal portions so as to allow deployment of the distal portion of the implantable carrier and at least one distal stent segment while a second portion of the implantable carrier remains unexpanded within the sheath. These limitations are not described in the cited references. Independent claims 1, 32, 41 and the claims which depend therefrom are therefore patently distinguishable from the cited references, thus overcoming the provisional double patenting rejection.

### Claim Objections

Claims 27 and 29 were objected to for lack of antecedent basis in the limitation "one of the stent segments." Claims 27 and 29 have been amended to recite "at least one of the plurality of stent segments" in order to overcome the objection and provide sufficient antecedent basis in the claim as well as to clarify the relationship between "each membrane" and "one of the stent segments."

Claims 22, 23, 28 and 37 were objected to as being unclear. Claims 22, 23, 28 and 37 have been amended to recite "the plurality of stent segments" instead of "the stent segments" in order to overcome the objection, clarify the claims and to be consistent with the claim language of claim 1.

### Claim Rejections under 35 U.S.C. § 103(a)

Claims 1-3, 9-12, 16-18, 22-28, 32-37 and 41-44 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Chermoni, U.S. Publication No. 2002/0156496 (hereinafter referred to as Chermoni) in view of DiCaprio, U.S. Patent No. 6,123,712 (hereinafter DiCaprio) in view of Konya. Such rejections are overcome as follows.

Claim 1 as amended, now recites in part the limitation that the implantable carrier is dividable at a plurality of locations along its length. Claim 1 as amended also now recites in part that the sheath is adapted to divide the implantable carrier at one of the locations and that the distal portion of the implantable carrier and the at least one stent segment are expanded while a

second portion of the implantable carrier remains unexpanded within the sheath. Support for this amendment may be found throughout the originally filed disclosure and in particular with reference to paragraph 0027, lines 14-15 and Figs. 4B-4C. The cited references fail to teach or suggest these newly added limitations.

Chermoni describes a positioner for moving one or more stents relative to a balloon from a first position in which the stent does not surround the balloon to a second position in which the stent surrounds the balloon. Abstract. The positioner in Chermoni is neither implantable nor is it dividable as now required by amended claim 1. Chermoni also fails to describe a sheath that is adapted to divide an implantable carrier. Furthermore, Chermoni fails to describe deploying a first portion of an implantable carrier and a stent segment thereon while a second portion of an implantable carrier remains unexpanded within a sheath, as now required by amended claim 1.

DiCaprio describes the use of a guide catheter (11 in Fig. 2), however, DiCaprio fails to describe that this guide catheter is a sheath adapted to divide the implantable carrier. DiCaprio also fails to describe that the distal portion of the implantable carrier and the at least one stent segment disposed thereon are delivered while a second portion of the implantable carrier remains unexpanded within the sheath.

Konya describes a multi-stage graft for implantation into a blood vessel. Abstract. In the Office Action, the Examiner characterized Konya as having a graft membrane that "comprises multiple dividable or frangible connections in that it is capable of being ripped, or torn, or cut and therefore divided...." Applicants respectfully disagree with this characterization. Dividing the graft in Konya would require bisecting the graft cover as well as either an anchoring stent, a scaffolding stent or a longitudinal connecting strut between stent segments. The graft therefore could not be ripped or torn and cutting it would destroy the graft by reducing its structural integrity where metal struts or stent segments have been divided as well as leaving sharp edges which could disrupt blood flow or cause vessel trauma. Even assuming *arguendo* that the graft could be divided without destroying it, a portion of the graft would not be left unexpanded within a sheath. Konya fails to teach how dividing the graft could be performed or how a portion of the graft could be deployed while a second portion is retained in the sheath.

Thus, Konya fails to disclose or suggest a dividable and implantable carrier, with a portion of the carrier left unexpanded in a sheath.

Additionally, there is no motivation to combine Chermoni with DiCaprio. DiCaprio describes a securement means such as a corrugated tube mounted on an inner shaft beneath a balloon. Abstract. The securement means provides a stent with a substrate seat with increased friction that maintains the stent on the catheter during delivery. Abstract. Chermoni describes a stent positioner. Abstract. In Chermoni, there is no need for the additional substrate seat with increased friction described in DiCaprio because the stent in Chermoni already is held in the stent positioner. Therefore, there is no motivation to combine Chermoni with DiCaprio.

Because the cited references alone or in combination fail to teach or suggest all of the claim limitations, and there is no motivation to combine references, *prima facie* obviousness under 35 U.S.C. § 103(a) is not established. Applicants therefore respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection and allowance of independent claims and the dependent claims which depend therefrom.

Independent claims 32 and 41 have also been amended to recite similar limitations as described above with respect to independent claim 1. Hence, claims 32 and 41 and the claims which depend therefrom should be allowed for several of the reasons discussed above with respect to claim 1.

Claims 13, 29 and 38 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Chermoni in view of DiCaprio in view of Konya and further in view of Letendre, U.S. Patent No. 6,267,783 (hereinafter referred to as Letendre). As discussed above, Chermoni fails to disclose or suggest a sheath that is adapted to divide an implantable carrier. Chermoni also fails to describe deploying a first portion of an implantable carrier and a stent segment thereon while a second portion of an implantable carrier remains unexpanded within a sheath. Letendre fails to supply the elements missing from Chermoni. Letendre describes a precursor stent for positioning within a blood vessel and coupleable to a graft for directing blood flow through an aneurysm. Abstract. Letendre does not describe a dividable implantable carrier nor does Letendre describe a sheath that is adapted to divide the implantable carrier.

Claims 13, 29 and 38 include the limitations of independent claims 1 or 32 which have been amended as previously described above, to include the limitations of a dividable implantable carrier and a sheath is adapted to divide the carrier. Therefore, the cited references alone, or in combination fail to teach or suggest all of the limitations of claims 13, 29 and 38.

Additionally, there is no motivation to combine Letendre with Chermoni, DiCaprio or Konya. The positioner in Chermoni moves stents from a first position in which the stent does not surround the balloon to a second position in which the stent surrounds the balloon. Abstract. The Chermoni system is designed to treat several stenoses in a single session and preferably carries a plurality of stents. Page 1, paragraph 0005. There is no motivation to combine Chermoni with Letendre because only a single precursor stent is utilized in Letendre and thus there is no need or motivation to use a multi-stent delivery system as described by Chermoni.

Furthermore, there is no motivation to combine Letendre with DiCaprio. The Letendre stent is easily recaptured and repositioned as indicated by the title of the patent. DiCaprio describes a securement means to maintain the stent on the catheter for control during delivery. Abstract. If the Letendre stent was not properly delivered, it could easily be recaptured and then repositioned. Thus there is no need to control the stent during delivery using the securement means described by DiCaprio and hence there is no motivation to combine Letendre with DiCaprio.

Additionally, there is no motivation to combine Letendre with Konya. Letendre describes a precursor stent for coupling with a graft to direct blood flow through an aneurysm. Abstract. Konya describes a multi-stage graft system wherein the second stage achieves a reliable seal between the vessel wall and the graft. Col. 12, lines 14-19. Because the Konya device achieves a reliable seal between the vessel wall and the graft, blood flow is directed into the graft and there is no need for an additional device to help direct blood flow through the aneurysm as Letendre describes. Hence, there is no motivation to combine Letendre with Konya.

Claims 14, 15, 30, 31, 39 and 40 were rejected under 35 U.S.C. §103(a) as being unpatentable over Chermoni in view of DiCaprio in view of Konya and further in view of Barry,

U.S. Publication No. 2002/0037358 (hereinafter referred to as Barry). As previously discussed above, Chermoni, DiCaprio and Konya all fail to disclose or suggest a sheath that is adapted to divide an implantable carrier. Chermoni, DiCaprio and Konya also fail to describe deploying a first portion of an implantable carrier and a stent segment thereon while a second portion of an implantable carrier remains unexpanded within a sheath. Barry describes a device for delivering drugs to tissue within the body. Abstract. Therefore, Barry fails to supply the elements missing from Chermoni, DiCaprio and Konya.

Barry fails to describe, teach or suggest a dividable implantable carrier. Nor does Barry describe a sheath that is adapted to divide the implantable carrier. Claims 14, 15, 30, 31, 39 and 40 include these limitations because they depend indirectly from independent claim 1 or 32 which have been amended as previously described. Therefore, the cited references alone, or in combination fail to teach or suggest all of the limitations of claims 14, 15, 30, 31, 39 and 40.

Furthermore, there is no motivation to combine DiCaprio with Chermoni. The securement means in DiCaprio maintains a stent on a catheter during delivery by providing the stent with a substrate seat with increased friction. Abstract. The stent positioner in Chermoni does not need an additional substrate seat with increased friction since this is already provided by the stent positioner. Therefore there is no motivation to combine DiCaprio with Chermoni.

Because the cited references alone or in combination fail to teach or suggest all of the claim limitations and there is no motivation to combine all of the references, *prima facie* obviousness under 35 U.S.C. § 103(a) is not established. Absent such a showing, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection and allowance of claims 13, 14, 15, 29, 30, 31, 38, 39 and 40.

New claim(s)

New claim 46 has been added. Support for this claim may be found in claim 11 and hence no new matter has been added. Applicants believe that this new claim is patentable over the cited references for the following reasons. Dependent claim 46 includes the limitations of amended independent claim 1, which has been distinguished from the cited references in the discussion above.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,

Jeffrey J. Grainger  
Reg. No. 36,815

By: James M. Heslin  
Reg. No. 29,541

TOWNSEND and TOWNSEND and CREW LLP  
Two Embarcadero Center, Eighth Floor  
San Francisco, California 94111-3834  
Tel: 650-326-2400  
Fax: 415-576-0300  
Attachments  
D3P:jke  
60952718 v1